

for the clinical study

Comparing the Efficacy of a Dual-Frequency Laser-Emitting Device, the "Invisared-RED Elite", With a Sham Device as Therapy for the Loss of Adipose Tissue (Body Fat) and Aesthetics in Overweight Individuals

NCT03811093

December 3, 2018

Invisa-RED Elite Clinical Trial Protocol

IRB Approved at the
Protocol Level
Dec 03, 2018

Sponsor:

Stephen Joseph Reardon
AES International LLC
590 Wentworth Dr. NW
Acworth, GA 30102
(404) 573-8993

Investigator:

Dr. Lynn Lavook Cross
Cross Chiropractic Center
1920 Northpoint Blvd, Suite 118
Hixson, TN 37343
(423) 322-8232

Purpose of the Study

The trial is designed to provide the empirical data to compare the efficacy and safety of the invisa-RED Technology Elite Low-level Laser Therapy (LLLT) device with a sham device when used in the treatment of individuals for weight loss and aesthetics. At the conclusion of the trial; the change in body fat percentage, and the weight and inches lost of the two groups will be statistically analyzed to determine the efficacy of the invisa-RED Technology Elite in weight loss and/or aesthetics therapy.

Background

“An estimated 160 million Americans are either obese or overweight. Nearly three-quarters of American men and more than 60% of women are obese or overweight. These are also major challenges for America’s children – nearly 30% of boys and girls under age 20 are either obese or overweight, up from 19% in 1980. Health risks such as cardiovascular disease, cancer, diabetes, osteoarthritis, and chronic kidney disease increase when a person’s BMI exceeds 23. In 2010, obesity and overweight were estimated to have caused 3.4 million deaths globally, most of which were from cardiovascular causes. Research indicates that if left unaddressed, the rise in obesity could lead to future declines in life expectancy in countries worldwide.” Christopher J.L. Murray *Professor, IHME Director, Chair, Department of Health Metrics Sciences*

The invisa-RED Technology Elite device has been developed to assist in weight loss therapy that counters these trends.

Criteria for Participants

The number of participants is projected to be forty (40).

There will be an equitable distribution of male and female participants.

Women who are pregnant, trying to get pregnant, or nursing will be excluded from the study, as they should not receive Low-level Laser Therapy (LLLT). There is no evidence of harm to an unborn baby however there have been no safety tests either, so for medical legal reasons we recommend never treating such individuals.

The participants will be between the ages of 18-65 years.

The ethnicity of the participants will be equitably distributed.

Inclusion criteria will be individuals that may benefit from a weight loss therapy.

Exclusion criteria will include the following:

- If you are pregnant, trying to get pregnant or nursing laser light therapy should be received only after the end of these conditions. There is no evidence of harm to a an unborn baby however there have been no safety tests either, so for medical legal reasons we recommend never treating areas directly over a developing child.
- Individuals with hypertension, light sensitive epilepsy, cancer, heart disease, infectious skin disease, and severe varicose veins should not use this device.
- People suffering from infectious and acute disease such as a fever should not use this device.
- People who have hemorrhagic disease, vascular ruptures, skin inflammation, or any disease of the skin should not use this device.
- People who have immune system dysfunction such as Leukemia, Hemophilia, etc., and light sensitive persons should not use this device.
- Individuals with a history of melanoma, raised moles, suspicious lesions, keloid scar formation, or healing problems should not undergo laser light therapy.
- Individuals with active infections, open lesions, hives, herpetic lesions, cold sores, or tattoos and permanent make-up in the area of treatment should not undergo laser light therapy.
- People who have used isotretinoin (commonly known as Accutane), tetracycline, St. John's Wort, or any photo sensitizing drugs in the last year should not undergo laser light therapy.
- Individuals with autoimmune diseases such as Lupus, Scleroderma, or Vitiligo should not undergo laser light therapy.
- Individuals who have pacemakers or other electro-stimulation devices surgically implanted should not undergo laser light therapy.
- Any insulin dependent individual should consult their physician before undergoing laser light therapy.
- All individuals considered "vulnerable" such as children, pregnant women, nursing home residents or other institutionalized persons, students, employees, fetuses, prisoners, and persons with decisional incapacity.

Methods and Procedures

The trial is designed to prove the efficacy and safety of the invisa-RED Technology Elite Low-level Laser Therapy (LLLT) device. The trial will compare results between two groups; the first will be treated using a fully functional invisa-RED Technology Elite device; this group will be internally designated the Usual Care Group. The second, a control group, will be treated utilizing a nonfunctional invisa-RED Technology Elite device; this group will be referred to internally as the Sham Group.

The sham device will consist of an invisa-RED Technology Elite device that will appear to operate as the Usual Care Group device to the operator, but the laser diodes will be disabled and will receive no power. If staff or a participant questions the efficacy of the sham device, an assertion may be made that only a near infrared, nonvisible frequency of light, is being employed.

The trial will be conducted employing a double blind study methodology; participants will be randomly assigned to each group through a drawing, neither participants nor clinicians will know to which trial group they are assigned. To ensure the double blind; treatment for the two groups will occur on separate days of the week. All participants will receive therapy at the Cross Chiropractic Center located in Hixson, TN. Group 1 will be assigned Monday, Wednesday, Friday, and Group 2; Tuesday, Thursday, and Saturday. Additionally staff administering the trial therapy will be assigned to work with one (1) group exclusively.

A simplified weight loss protocol will be employed based on the "Consultation Protocol" from the invisa-Red Training Manual. All study participants will undergo nine (9) therapy sessions of 20 minutes each; using a singular protocol setting for pulse (3.5s) and delay (0.2s), but power settings will be based on the participants Fitzpatrick Scale skin type. For skin types i and ii a power setting of 7 will be used, for skin types iii and iv a power setting of 6, for skin types v and vi a power setting of 4 will be employed. At the conclusion of the nine (9) therapy sessions; the change in body fat percentage, weight, and inches lost of the two groups will be statistically analyzed to determine the efficacy of the invisa-RED Technology Elite as a weight loss therapy. Any medical errors will be included in the statistical analysis.

Staff Training and Certification

All staff involved in conducting the clinical trial will undergo training and be certified on the use, safety, and clinical procedures of the invisa-RED Technology Elite.

Data Analysis and Data Monitoring

The measured weight loss and total inches lost per participant from the two groups will be statistically evaluated using an Independent T-Test with a P value of .05.

The study is classified as a minimal risk trial of short duration therefore a detailed plan for monitoring the data for participant safety is not required.

Data Storage and Security

All individuals participating in the trial will be assigned a participant number. Subsequently all clinical records and reports will reference only the participant number, ensuring that participants remain anonymous.

Because of the low number of trial participants, only paper records will be maintained for all clinical and personal data. Records will be kept in locked storage and physical access will only be on a need to know basis. A participants' personal data correlating the participating individuals name and the trial participants Identifying Number will only be available to the principal investigator and trial administrator. All analytics will be performed using only data masked or redacted of any personal information.

Risk/Benefit Assessment

Applying the test for the determination of risk established by the FDA Regulation referred to as the "Common Rule" found in 45 CFR 46, Subpart A the rule states;

"Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

We have determined that only a minimal risk is presented to participants of the trial and therefore believe a finding that the device as used in this research is Non-Significant Risk and thus qualifies for an abbreviated IDE under 21 CFR 812.2(b).

See the detail minimal risk criteria analysis below:

- i. The device is NOT intended as an implant that presents a potential for serious risk to the health, safety, or welfare of a subject.
The invisa-RED Elite employs no implanted devices as part of any treatment or therapy.

- ii. The device is NOT purported or represented to be for a use in supporting or sustaining human life that presents a potential for serious risk to the health, safety, or welfare of a subject.
The invisa-RED Elite is only to be used as directed for weight loss therapy and aesthetics and is not represented or employed as a life sustaining device or therapy.

- iii. The device is NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health that presents a potential for serious risk to the health, safety, or welfare of a subject.
The invisa-RED Technology Elite is to be used only as directed for weight loss therapy and aesthetics. If weight loss is the goal of the therapy, the treatments should be a part of a holistic weight loss program, which may include diet, exercise, and behavior modification in the form of counseling or group therapy.

- iv. The device does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject.
The invisa-RED Elite is classified as an FDA Class II device and has passed all FDA electromagnetic compatibility (EMC) standards.

The invisa-RED Elite device employs Class 3b laser diodes in a system of "paddles" each containing multiple diodes. Class 3B lasers are hazardous for eye exposure; therefore during therapy protective eyewear is recommended for staff, the individual undergoing treatment, and any others in the room. Eye safety is further enhanced by standard invisa-RED Elite clinical procedures, which are designed to eliminate exposure of the eyes of the patient and proximate individuals to direct laser light. These clinical procedures dictate that the paddles are to be 1) placed on the area to be treated, 2) secured if required, and then and only then 3) the system is activated and treatment begun. This eliminates the chance of any direct laser light entering the eye.

Class 3B lasers can heat skin and materials but are not considered a burn hazard. However treatment protocol standards found in the users manual do recommend power settings, pulse and delay be adjusted for the patients Fitzpatrick Scale skin type; as differing skin tones result in a variable coefficient of absorption of electromagnetic energy. If these recommendations are not followed, the therapy may result in mild sunburn like effect and or skin sensitivity. Additionally each patient is asked to verbally attest to his or her comfort level at the start of each therapy session and further instructed to notify staff of any discomfort at any time.

As stated in the user manual and stressed during invisa-RED Elite device Training and Certification the following contraindications and precautions for patients will apply:

- *If you are pregnant, trying to get pregnant or nursing laser light therapy should be received only after the end of these conditions. There is no evidence of harm to a an unborn baby however there have been no safety tests either, so for medical legal reasons we recommend never treating areas directly over a developing child.*
- *Individuals with hypertension, light sensitive epilepsy, cancer, heart disease, infectious skin disease, and severe varicose veins should not use this device.*
- *People suffering from infectious and acute disease such as a fever should not use this device.*
- *People who have hemorrhagic disease, vascular ruptures, skin inflammation, or any disease of the skin should not use this device.*
- *People who have immune system dysfunction such as Leukemia, Hemophilia, etc., and light sensitive persons should not use this device.*
- *Use of laser light therapy in the ears, nose, eye, or throat is not recommended.*
- *Individuals with a history of melanoma, raised moles, suspicious lesions, keloid scar formation, or healing problems should not undergo laser light therapy.*
- *Individuals with active infections, open lesions, hives, herpetic lesions, cold sores, or tattoos and permanent make-up in the area of treatment should not undergo laser light therapy.*
- *People who have used isotretinoin (commonly known as Accutane), tetracycline, St. John's Wort, or any photo sensitizing drugs in the last year should not undergo laser light therapy.*
- *Individuals with autoimmune diseases such as Lupus, Scleroderma, or Vitiligo should not undergo laser light therapy.*
- *Individuals who have pacemakers or other electro-stimulation devices surgically implanted should not undergo laser light therapy.*
- *Any insulin dependent individual should consult their physician before undergoing laser light therapy.*

All prospective participants interviewed for the trial will be vetted using the invisaRED Technologies Elite guidelines of indications and contraindications. Upon following all guidelines for indications and contraindications and employing both standard procedures for eye safety and treatment protocols, a participant's risk may best be compared to exposure to direct sunlight.

Subjects of the study receiving the invisaRED Technologies Elite therapy may receive the following health and aesthetic benefits:

- Body fat reduction through laser assisted lipolysis or *photobiostimulation which has been shown to increase cellular metabolism
- Sculpting of targeted body areas through adipose tissue reduction and skin tightening.
- Stretch mark fading
- Elimination or reduction of cellulite
- Skin tightening and enhanced collagen production
- Increase blood flow to areas of epidermis, dermis, hypodermis, and connective tissue to stimulate cellular respiration
- Detoxification due to improved blood circulation and stimulation of lymphatic transport.

Subject Identification, Recruitment And Consent/Assent

At roadway intersections in close proximity to the Cross Chiropractic Clinic signage will be erected containing the verbiage: "Weight Loss Clinical Study, 40 Participants, (404) 909-0578" in order to recruit study volunteers from the community.

The clinic's patients will be provided an opportunity to volunteer for consideration as a trial participant.

The primary investigator will conduct all subject interviews and obtain informed consent. A thorough disclosure of all clinical process, contraindications, and any risk will be discussed with candidates for the trial.

All candidates will be older than the age of majority in the state of Tennessee (18 years old) but none shall be older than 65 years of age.

No candidates of diminished capacity will be considered for inclusion in the trial.

Capacity is a functional assessment and a clinical determination about a specific decision that can be made by any clinician familiar with a patient's case. The four key components addressed during the candidates capacity evaluation include: 1) communicating a choice, 2) understanding, 3) appreciation, and 4) rationalization/reasoning.

There shall be no cost incurred by candidates for inclusion in the study or individuals selected to participate in the study.

No monetary remuneration will be offered participants in the study. However an offer will be made "post blind" to the participants who received treatment using the sham device for an additional nine (9) sessions of treatments using a fully functional invisa-RED Technology Elite device. This offer will provide the participants treated with the sham device the opportunity to benefit from the weight loss and aesthetics therapy.

Requirements for Human Subject Protection Training

The Primary Investigator and clinical associates conducting the trial will complete the Collaborative Institutional Training Initiative (CITI) course GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus).